K120244

NEXERA MEDICAL

JUL 5 2012

Section 5.0: 510(k) SUMMARY

510(k) Owner: NexEra Medical, Inc.
3343 West Commercial Blvd, Suite 103
Ft. Lauderdale, FL 33309

Contact: Paul Sallarulo, President CEO
Phone: 954-495-2020, x 2031
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Establishment Registration Number: TBD

Date Summary Prepared: July 2, 2012

Device:

Trade Name:	SpectraShield model 9500 Surgical Mask
Common /Classification Name:	Surgical mask
Classification Product Code:	ONT
Regulation Number:	21CFR 878.4040

Predicate Device Information: K090414 SpectraShield 9500 Surgical N95 Respirator

Device Description: The SpectraShield model 9500 Surgical Mask is a molded shape surgical mask composed of 4 layers of material, molded to form the mask. A 2-ply meltblown polypropylene middle layer is sandwiched by inner and outer layers of 100% polyester nonwoven fabric. The inner and outside layers of polyester nonwoven fabric include fibers that have been embedded with an antibacterial agent to provide antibacterial performance. The mask has 2 latex-free non-allergenic elastic straps and an aluminum nose strip.

Intended Use: The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, **tested for continuous use up to 8 hours,** embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the

surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions.

No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.

The SpectraShield 9500 Surgical N95 respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.

510(k) Summary
Device Comparison Table

	New Device	Predicate Device
510(k) #	To be determined	K090414
Company	NexEra Medical, Inc.	NexEra Medical, Inc.
Name/Model	**SpectraShield 9500 Surgical N95 Respirator *** (*with amended Intended use Statement)	**SpectraShield 9500 Surgical N95 Respirator**
Fabrics	Nonwoven polyester containing a silver-copper zeolite (antibacterial agent) and a meltblown polypropylene substrate.	Nonwoven polyester containing a silver-copper zeolite (antibacterial agent) and a meltblown polypropylene substrate.
Nosepiece	100% Aluminum	100% Aluminum
Straps	(2) Polyamide fiber and elastic straps, latex free	(2) Polyamide fiber and elastic straps, latex free
Mask Style	Molded shape	Molded shape
Fluid Resistance ASTM F1862	Pass: Fluid Resistant @ 160mm Hg	Pass: Fluid Resistant @ 160mm Hg

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	New Device	Predicate Device
Particulate Filtration Efficiency ASTM F2299	Pass: 99.87% at 0.1 microns	Pass: 99.87% at 0.1 microns
Differential Pressure Mil M36954C	Pass: 4.3mm H_20/cm^2	Pass: 4.3mm H_20/cm^2
Bacterial Filtration Efficiency ASTM F2101	Pass: 99.9%	Pass: 99.9%
Flammability Class 16CFR 1610	Class 1	Class 1
Cytotoxicity 10993-10	Pass: USP reactivity score = < 2	Pass: USP reactivity score = < 2
Primary skin irritation ISO10993-10	Pass: PSI Score = 0, Non-irritant	Pass: PSI Score = 0, Non-irritant
Repeated Patch Dermal Sensitization ISO 10993-10	Pass: 0% incidence sensitization response "0" severity at each evaluated time point.	Pass: 0% incidence sensitization response "0" severity at each evaluated time point.
Systemic Toxicity ISO 10993-11	Pass: No mortality or evidence of systemic toxicity from the extracts was observed.	Pass: No mortality or evidence of systemic toxicity from the extracts was observed.
Physico-chemical USP Physico-chemical Test-Plastics	Pass: Test results met the USP limits.	Pass: Test results met the USP limits.
Gas off Testing	Total antibacterial particles released from the device were verified to be within safe inhalation levels.	Total antibacterial particles released from the device were verified to be within safe inhalation levels.
Leach off testing	Total leachable antibacterial particles released from the device were verified to be	Total leachable antibacterial particles released from the device were verified to be

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	New Device	Predicate Device
	within safe orally ingestible levels.	within safe orally ingestible levels.
BioEfficacy :	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.40log_{10}reduction - 1 hour *H.influenzae*: > 6.20log_{10}reduction - 1 hour MRSA: > 4.83log_{10}reduction - 1 hour	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.40log_{10}reduction - 1 hour *H.influenzae*: > 6.20log_{10}reduction - 1 hour MRSA: > 4.83log_{10}reduction - 1 hour
BioEfficacy : after repeated exposures to perspiration over 12 hours	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.25log_{10}reduction - 1 hour *H.influenzae*: > 4.18log_{10}reduction - 1 hour MRSA: > 4.11log_{10}reduction - 1 hour	T_0 Inoculums measured, $>10^6$ *S.pyogenes*: > 4.25log_{10}reduction - 1 hour *H.influenzae*: > 4.18log_{10}reduction - 1 hour MRSA: > 4.11log_{10}reduction - 1 hour
Intended Use Statement	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, **tested for continuous use up to 8 hours**, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.	The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable surgical N95 respirator, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. No clinical studies have been conducted comparing the ability of the untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator. The SpectraShield 9500 Surgical N95

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	New Device	Predicate Device
	The SpectraShield 9500 Surgical N95 respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.	respirator is a single use device intended for occupational use to protect against microorganisms, body fluids and particulate material.

Conclusion: The subject device (SpectraShield model 9500 Surgical mask with the revised IFU referencing "tested for continuous use up to 8 hours"), and the predicate device (K090414) are the same device. The intention of this 510k submittal is to change the IFU to include the statement **"tested for continuous use up to 8 hours".**

The predicate device (K090414) was tested for bio-efficacy after repeated exposures to perspiration over a 12 hour period (see K090414 Repeat Challenge Protocol and Testing). The repeat challenge testing required the predicate device be repeatedly exposed to perspiration over a 12 hour period. Following the 12 hour exposure the predicate device was tested and demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against *Streptococcus pyogenes*, MRSA (Methicillin Resistant *Staphylococcus aureus)*, and *Haemophilus influenzae* under tested contact conditions. The intention of the repeated challenge and sustained exposure was to demonstrate that the device would still function as intended (99.99% kill) after wearing the device for 12 hours.

The IFU for the predicate device references "single use, disposable device". The proposed change to the IFU would read "single use, disposable device, tested for continuous use up to 8 hours."

It is our conclusion that the proposed change to the IFU does not change the intended use of the device, and we believe the change to the IFU further clarifies the intended use of the device. Additionally, we note the proposed change to the IFU demonstrate the device is as safe and as effective as the predicate device and performs equally as well.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 5 2012

Mr. Paul Sallarulo
Nexera Medical Incorporated
3343 West Commercial Boulevard Suite 103
Fort Lauderdale, Florida 33309

Re: K120244
Trade/Device Name: SpectraShield Model 9500 Surgical Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: ONT
Dated: June 21, 2012
Received: June 25, 2012

Dear Mr. Sallarulo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4.0: Indications for Use Statement

510(k) Number: 510(k) submission K12 0244

Device Name: SpectraShield model 9500 Surgical Respirator

Indications for Use:

The SpectraShield 9500 Surgical N95 Respirator is a single use, disposable, surgical N95 respirator, tested for continuous use up to 8 hours, embedded with a zeolite carrier containing a silver-copper agent on the outer layer and is not an antimicrobial drug. SpectraShield 9500 kills 99.99% of test bacteria after one hour of contact with the surface of the respirator. In vitro (laboratory) tests have demonstrated 99.99% kill on the surface of the outer layer of the respirator when tested in vitro against single isolates of the following test bacteria: Streptococcus pyogenes, MRSA (Methicillin Resistant Staphylococcus aureus), and Haemophilus influenzae, under tested contact conditions.

No clinical studies have been conducted comparing the ability of an untreated surgical N95 respirator and the SpectraShield model 9500 surgical N95 respirator to protect the wearer from infection, and the antibacterial treatment cannot effect pathogens that are inhaled around the edges of the respirator.

The SpectraShield 9500 Surgical N95 respirator is a single use device, intended for occupational use to protect against microorganisms, body fluids, and particulate material.

Prescription Use _____ AND/OR Over –the-counter Use _X_
(21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120244